



(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Nitesh Ratnakar MD

Application No: 10/711,859

Confirmation No.: 5858

Filed: October 11, 2004

Art Unit: 3739

For: DUAL VIEW ENDOSCOPE

Examiner: John P. Leubecker

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is responsive to the Examiner's Answer mailed on August 16, 2010, and the Final Rejection (*hereinafter*, Final Rejection) mailed November 13, 2009 of claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 54-57, and 61-74. A Notice of Appeal was timely filed on February 9, 2010.

This is a Reply Brief under Rule 41.41 responding to the Examiner's Answer. Each of the topics of Rule 41.37 is presented herewith.

I. Real Party in Interest

The real party in interest for this appeal is Nitesh Ratnakar MD, dba Novation Sciences LLC, having its principal place of business at Route 3, Box 179A; Elkins WV 26241 (this is a physical address and not a Post Office Box).

II. Related Appeals and Interfaces

There are no other appeals or interfaces which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 54-57, and 61-74 are currently pending in the present application and all stand fully rejected. Claims 2, 4-9, 11, 14, 17-42, 45-46, 51-53, and 58-60 were previously canceled and claim 48 was previously withdrawn. Applicant appeals from the continued rejection of claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 54-57, and 61-74, which claims are presented in Appendix A, Claims Appendix.

IV. Status of Amendments

After receiving the Final Rejection, Appellant filed a Notice of Appeal on February 9, 2010. The claim amendments submitted on July 27, 2009 were entered in full.

V. Summary of Claimed Subject Matter

The presently claimed subject matter includes various devices. The following is a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, as required by 37 C. F. R. § 41.37(c)(1)(v). In general, the following explanation is not intended to be used or construed or limit the claims, which are believed to speak for themselves, nor does Appellant intend the following explanation to modify or add any claim elements, or to constitute a disclaimer of any equivalents to which the claims would otherwise be

entitled, nor is any discussion of certain preferred embodiments herein intended to disclaim other possible embodiments. References herein to the specification are intended to be exemplary and not limiting. Reference numbers provided are reference numbers used in Appellant's specification and drawings.

An embodiment of independent claim 1 includes an endoscope (FIG. 1, paragraph [0055]) that includes a shaft extending along a longitudinal axis (1 FIGS. 17-19, paragraph [0086]), having a distal end ((14) FIGS. 18 and 19, paragraph [0086]) receivable in a hollow organ ((41) FIGS. 4A and 4B, paragraphs [0022], [0023], [0059], and [0060]) and a proximal end ((10) FIG. 1, paragraph [0055]) and defining a hollow channel therethrough (25 FIGS. 18 and 19, paragraphs [0086] and [0087]), the shaft including a steering mechanism (18 FIG. 1, paragraph [0056]) for moving the distal end of the shaft from a first distal endoscope position to a second distal endoscope position (FIGS. 4A and 4B, paragraphs [0056], [0059], and [0060]);

a first lens (20, FIGS. 18 and 19, paragraph [0086]) selectively positioned adjacent to the distal end of the shaft (FIG. 19, paragraph [0086]) for receiving a first image in a first direction (FIG. 4A), the first direction generally being forward and parallel to the longitudinal axis of the shaft (32, FIG. 4A, paragraph [0059]) and the first image generally being a circumferential view of the hollow organ (32, FIG. 4A, paragraph [0059]);

a catheter (51, FIGS. 17-19, paragraphs [0085] and [0086]) receivable in the hollow channel of the shaft for extension and retraction therethrough (FIGS. 18 and 19, paragraphs [0085] and [0086]), the catheter including a catheter distal end (170, FIG. 17), a proximal section (FIG. 17, paragraph [0085]) and a bending section interposed between the distal end and the proximal section (FIG. 17, paragraph [0085]), wherein the bending section selectively permits retroflexion of the distal end from a first position to a second position upon extension of the distal end of the catheter from the hollow channel (FIGS. 17-19, paragraphs [0085] – [0087]); and

a second lens (52, FIG. 17, paragraph [0085]) coupled to the distal end of the catheter (FIG. 17, paragraph [0085]), the second lens selectively positionable with the distal end of the shaft in the second position so as to receive a second image in a second direction (FIG. 19), the second direction being at a generally 180 degree angle to the first direction (FIGS. 18 and 19)

and the second lens being selectively independently advanced generally parallel to the axis relative to the first lens (FIGS. 18 and 19).

An embodiment of independent claim 54 includes an endoscope (endoscope (FIG. 1, paragraph [0055]) including a first lens (20, FIGS. 18 and 19, paragraph [0086]) for selectively receiving a first image in a first direction and the first image being a view taken in the first direction (FIGS. 4A, 18, and 19, paragraphs [0086] and [0087]);

a shaft (1 FIGS. 17-19, paragraph [0086]) having a distal end ((14) FIGS. 18 and 19, paragraph [0086]) for fixedly receiving the first lens therein (paragraph [0055]), the shaft having an axis, defining a hollow channel therethrough (25 FIGS. 18 and 19, paragraphs [0086] and [0087]) and having a steering mechanism (18 FIG. 1, paragraph [0056]) to deflect the distal end for, at least in part, guiding the shaft within an organ (FIGS. 4A and 4B, paragraphs [0056], [0059], and [0060]);

a rear view module (51, FIGS. 17-19, paragraphs [0085] and [0086]) for receiving a second image in a second direction, the second direction being at an angle generally 180 degrees to the first direction (FIGS. 18 and 19) and the second image being a view in the second direction (FIGS. 18 and 19 paragraphs [0085] and [0086]), wherein the rear view module includes a second lens (52, FIG. 17, paragraph [0085]);

a catheter (51, FIGS. 17-19, paragraphs [0085] and [0086]) being reversibly received within the channel therethrough (FIGS. 18 and 19, paragraphs [0085] and [0086]) and having proximal (FIG. 17, paragraph [0085]) and distal (170, FIG. 17) ends and an actuation mechanism paragraph [0085]); wherein the catheter is selectively advanced within the channel such that the rear view module is advanced generally along the axis relative to and independent of the first lens (FIGS. 18 and 19, paragraphs [0085] and [0086]).

VI. Grounds of Rejection to be Reviewed on Appeal

- A. Whether claim 1 is indefinite under 35 U. S. C. § 112, second paragraph.
- B. Whether claims 1, 3, 10, 12, 13, 43, 44, 54-57, 61-63, and 66-74 are unpatentable under 35 U. S. C. § 103 under Kaiya (US Patent 5,178,130) in view of Torii, (US Patent 6,482,149).

- C. Whether claims 15, 16, 65 and 66 are unpatentable under 35 U. S. C. § 103 under Kaiya (US Patent 5,178,130) in view of Torii, (US Patent 6,482,149), and further in view of Yoon, (US Patent 6,066,090).
- D. Whether claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 54-57, 61, 62, and 64-67 are unpatentable under 35 U. S. C. § 103 over Yoon, (US Patent 6,066,090).

The issues presented in this reply are:

- Issue (a) The Clarity of Claim 1
- Issue (b) The “Distal End of the Shaft” of Yoon as identified by the Examiner
- Issue (c) Yoon does not teach a shaft that is steered
- Issue (d) Yoon does not teach a shaft having a channel and fixedly receiving a lens
- Issue (e) Yoon does not teach lenses that are advanced independently
- Issue (f) Kaiya teaches two scopes that view the same tissue
- Issue (g) The scopes of Kaiya are taught to only view the same tissue
- Issue (h) The Applicability of *In re Gordon* and *In re Ratti*
- Issue (i) Examiner’s Remarks evinces a clear misunderstanding of *In re Gordon*, especially considering the recent BPAI decision in *In re Chiang* (April 2010)
- Issue (j) KSR does not permit providing a motivation to defeat *In re Gordon*
- Issue (k) The Examiner’s ‘inherent’ modification to Kaiya
- Issue (l) Suggestion by a 35 USC §103 Reference
- Issue (m) Kaiya does not teach an actuator for the inner endoscope

VII. Argument

The remarks in arguments for Issue (a) pertain to claim 1. Each of the remarks in arguments for Issues (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), and (l) pertain to claims 1 and 54. The remarks in the argument for Issue (d) pertains to claims 54. The remarks in the argument for Issue (e) pertains to claim 1. The remarks in the argument for Issue (m) pertains to dependent claims 10 and 56.

The Examiner has erred in concluding that the recitations of claim 1 are indefinite. The Examiner has also erred regarding the teachings of Kaiya and Yoon, as well as the applicability of KSR as limited by *In re Gordon* and *In re Ratti*. Importantly, “If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue.” *In re Rouffet*.

A. The Law

1) 35 U.S.C. 112, second paragraph

The essential question under 35 U.S.C. 112, second paragraph, is whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. Definiteness of claim language is analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). See also MPEP 2173.02.

2) Inherency

The Federal Circuit has provided:

Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Mehl/Biophile International Corp. v. Milgraum, 52 USPQ2d 1303 at 1305 (Fed Cir. 1999) (*emphasis in original*).

3) All Elements must be taught or suggested

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j).

“The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

4) Teaching Away

“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out by the reference.” *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

5) Impermissible Modifications

If the proposed modification renders the prior art device unsuitable for its intended purpose, then the proposed modification is impermissible for *prima facie* obviousness. MPEP 2143.01, citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). If the proposed modification or combination of references would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

As recently as April 26, 2010, the Board of Patent Appeals and Interfaces (BPAI) has endorsed the applicable holding of *In re Gordon* (see *In re Chiang*, Appeal 2009-0146293 (application 10/921,604), page 5, where the BPAI cites *In re Gordon* along with *KSR*) while holding that an impermissible modification exists where the functionality of the modified device is rendered unsuitable (see *In re Chiang*, page 7).

6) References in their Entireties

In performing a 35 U.S.C. §103 analysis, it is error to consider “references in less than their entireties, i.e. in disregarding disclosures in the references that diverge from and teach away from the invention at hand.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In evaluating patentability, the question “is whether inventions, as set forth in claims” ... “as a whole, would have been obvious to one of ordinary skill in the art when they were made, in view of the teachings of the prior art as a whole.” *Stratoflex, Inc. v. Aeroquip Corporation*, 713 F. 2d 1530, 218 USPQ 871 (Fed. Cir. 1983).

7) KSR

The Supreme Court requires that an Examiner must provide “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). Further, the Court made clear that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. (*Id.*) There must be “something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.” *In re Rouffet*, 47 USPQ2d 1453 at 1457 (Fed Cir. 1998).

Impermissible use of the Appellant’s claim as a blueprint for “filling in the gaps” of the prior art is specifically prohibited by the Federal Circuit - “If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 at 1457 (Fed Cir. 1998).

“Rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be ‘an illogical and inappropriate process by which to determine patentability’.” *Id.* quoting *Sensonic, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

8) Therethrough

The plain meaning of “therethrough” is extending from one side to the other. *Sage Products Inc. v. Devon Industries Inc.*, 126 F.3d 1420, at 1431, (Fed. Cir. 1997)

B. The Issues

1 Rejection of Claim 1 under 35 U.S.C. § 112

Issue (a) Clarity of Claim 1

In the Examiner’s Answer, the Examiner maintains the 112 rejection of claim 1. In this 35 U. S. C. 112, second paragraph, rejection, the Examiner stated in the Final Rejection that:

As to claim 1, phrase “the second lens selectively positionable with the distal end of the shaft in the second position” (lines 16-17) is confusing since the second lens is recited as being coupled to the catheter (as opposed to the “shaft” of line 2). It appears that the word “shaft” should more properly be –catheter--.

Final Office Action mailed November 13, 2009, page 2, lines 8-11 (quotations in original).

As stated in the Appeal Brief of February 16, 2010, claim 1 is intended to recite the capability to take two different images from the perspective of opposite directions. Appellant maintains that the wording of claim 1 is clear.

Specifically, claim 1 positively recites “a first lens selectively positioned adjacent to the distal end of the shaft for receiving a first image in a first direction, the first direction generally being forward and parallel to the longitudinal axis of the shaft,” and “the second lens selectively positionable **with** the distal end of the shaft in the second position so as to receive a second image in a second direction.” (**emphasis** added) In the Examiner’s Answer, the Examiner contends that the “with” that is bolded in the previous quote should be “relative to” in order to properly convey the intended meaning of this recitation. However, “with the distal end of the shaft in the second position” is a prepositional phrase, and, as with prepositional phrases, may be moved within a sentence. As an example, the previous quote may be reworded to read “with the distal end of the shaft in the second position, the second lens selectively positionable so as to receive a second image in a second direction,” while not changing the meaning of the recitation. This rewording may aid in better understanding the confusion introduced when reading the “with” as an unsuccessful attempt to mean “with respect to.”

Therefore, the Examiner is reading the “with” of the previous quote as being a connector (intended to mean “with respect to”), whereas the “with” is clearly the beginning of a prepositional phrase. To be precise, the Examiner’s suggested wording within the Examiner’s Answer also correctly conveys the intended meaning of this capability. Also, the recitation could be reworded to read “the second lens selectively positionable **when** the distal end of the shaft is in the second position so as to receive a second image in a second direction,” or as “**when** the distal end of the shaft **is** in the second position, the second lens **is** selectively positionable so as to receive a second image in a second direction.”

Applicant respectfully submits that this recitation may be reworded in one of many variants while clearly and concisely conveying the intended capability. Further, Applicant submits that different readers may be confused by any of the variants and that the Applicant has met the burden under 35 U.S.C. 112 to particularly point and distinctly claim the subject matter which applicant regards as is the invention. For at least this reason, the 112 rejection of Appellant's claim 1 is improper.

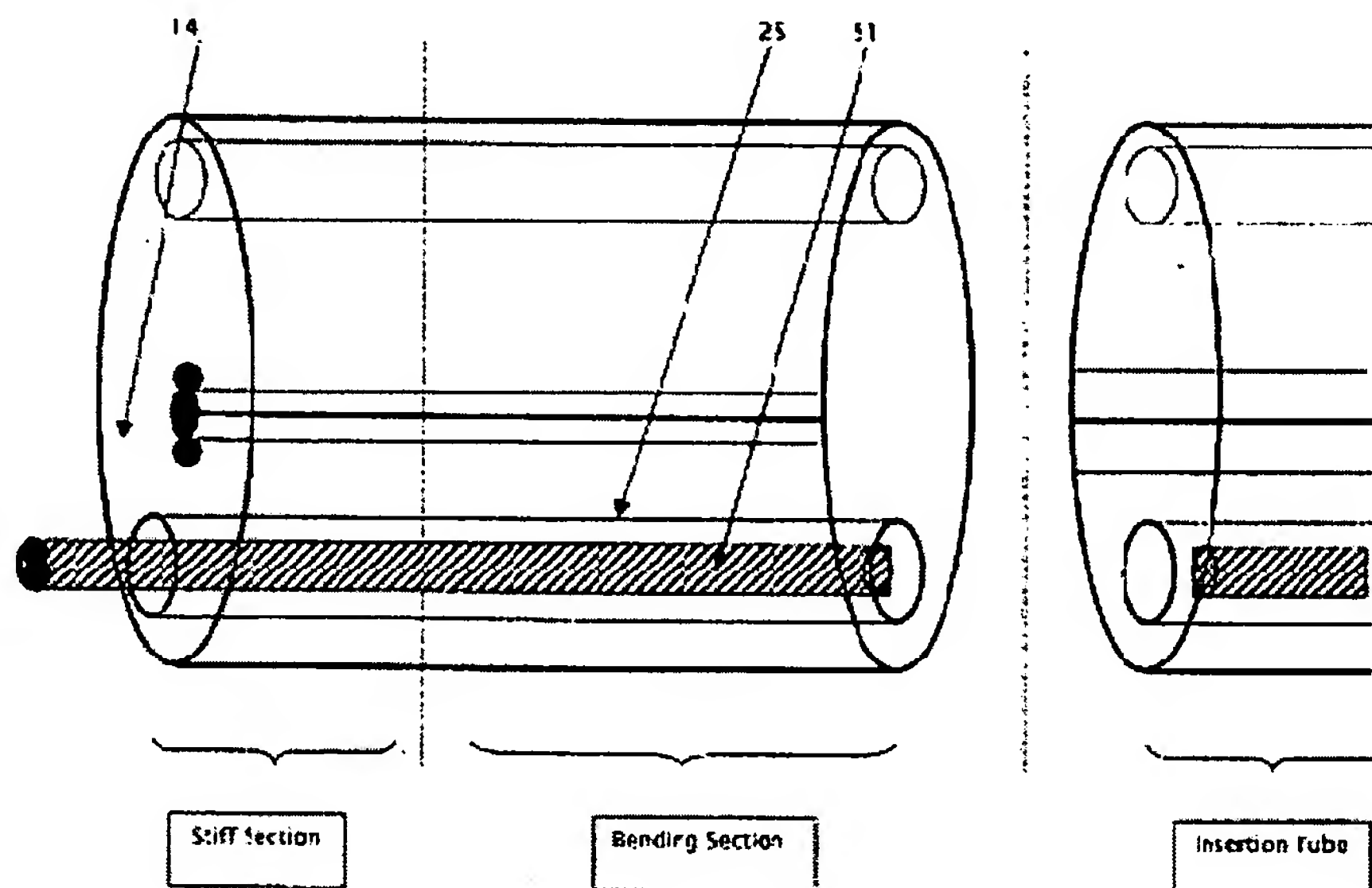


FIG. 18

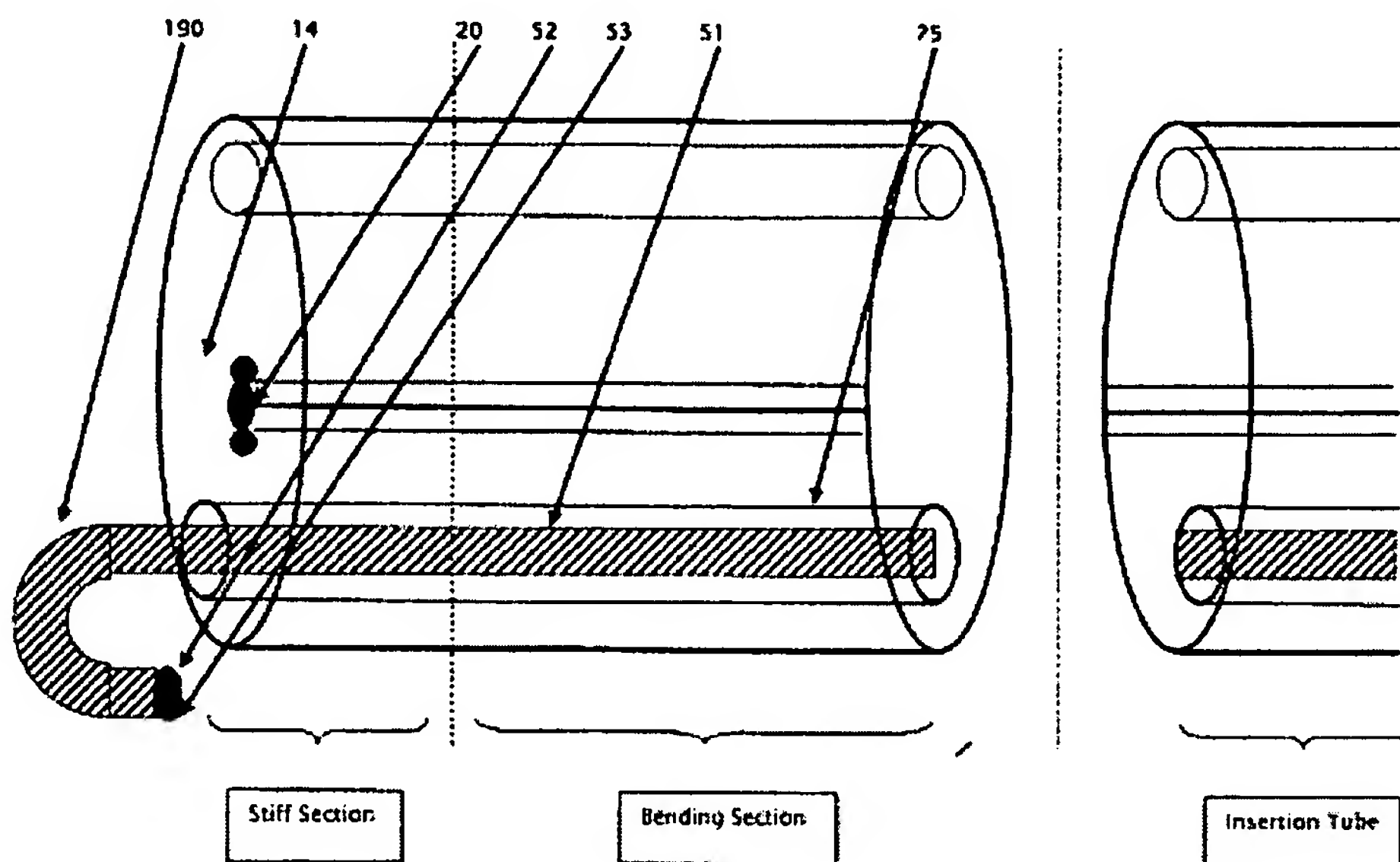


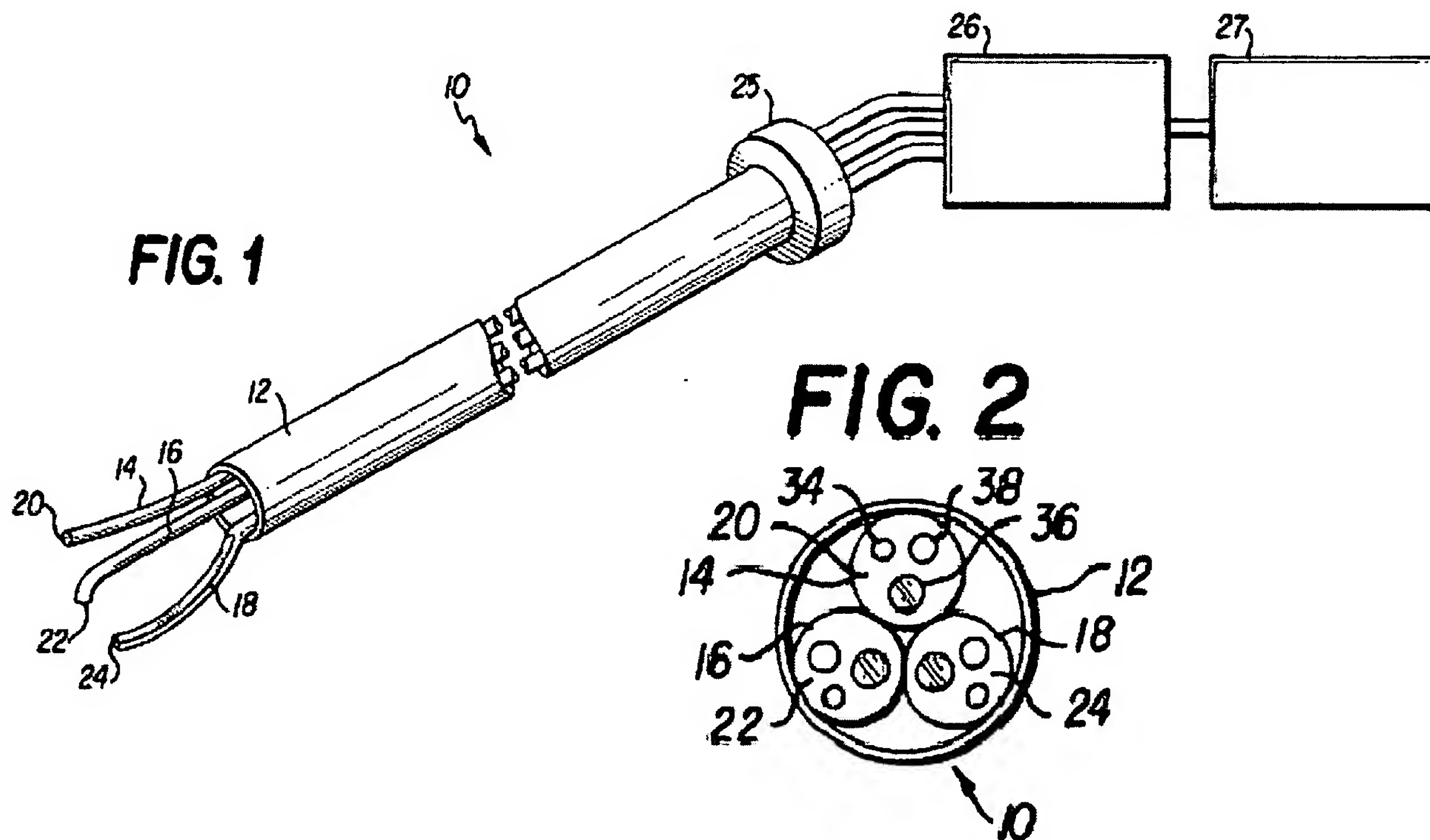
FIG. 19

2. Claim Rejections 35 U.S.C. § 103 (Yoon, All Elements)

Issue (b) The “Distal End of the Shaft” of Yoon as identified by the Examiner

Independent claim 1 recites “a *shaft* extending along a longitudinal axis, having a *distal end* receivable in a hollow organ *and a proximal end and defining a hollow channel therethrough.*” (*emphasis added*) Independent claim 54 recites “a *shaft having a distal end* for fixedly receiving the first lens therein, the shaft having an axis, defining a hollow channel *therethrough.*” (*emphasis added*) The Appellant respectfully submits that the term “therethrough” has been consistently employed in patent claims. More specifically, the Federal Circuit in *Sage Products* (126 F.3d 1420 at 1431, (1997)) identifies the plain meaning of therethrough as being “from one side . . . to the other.” Accordingly, the recitation “a shaft having a distal end . . . and a proximal end and defining a hollow channel therethrough” clearly recites that the channel extends from the distal end to the proximal end of the shaft. In contrast, the hollow channel of the body 12 of Yoon does not extend to the distal end 20 of the endoscope branch 14 of Yoon. (See FIG. 1 of Yoon, reproduced below)

In the In the Examiner's Answer, the Examiner contends that Appellant could have defined the hollow channel as extending 'through' the shaft, but chose not to. The Appellant submits that the clear meaning of the language used, if the term therethrough is properly defined, precludes the distal end 20 of the endoscope branch 14 of Yoon from being the distal end of the body 12. For at least this reason, the 35 U.S.C. §103 rejection of Appellant's pending claims under Yoon is improper.



Issue (c) Yoon does not teach a shaft that is steered

Independent claim 1 positively recites "a steering mechanism for moving the distal end of the shaft." Independent claim 54 positively recites "a shaft having a distal end ... and having a steering mechanism to deflect the distal end." The Examiner has identified the body 12 of Yoon as a hollow shaft (Final Action, page 6, line 14 to page 7, line 1) and contends that Yoon teaches that the "distal end of the shaft (14)" is "steerable" (Final Action, page 7, lines 1-3) and continues to demonstrate how the endoscope branch 14 of Yoon is steerable.

As detailed above in Issue (b), the endoscope branch 14 of Yoon is not the distal end of the shaft 12 of Yoon. At best, the endoscope branch 14 of Yoon is a steerable endoscope that is interposed through the shaft 12 of Yoon. Further, Yoon makes no mention of steering the shaft 12. Accordingly, the conclusion that the shaft 12 of Yoon has a distal end that is steerable is clear error. Therefore, the Examiner has failed to establish a prima facie case since all claim recitations are not taught in the prior art, as required in *In re Royka*. For at least this reason, the 35 U.S.C. §103 rejection of Appellant's pending claims under Yoon is improper.

Issue (d) Yoon does not teach a shaft having a channel and fixedly receiving a lens

Independent claim 54 positively recites “a shaft having a distal end for fixedly receiving the first lens,” “the shaft having an axis, defining a hollow channel therethrough,” and “the catheter is selectively advanced within the channel such that the rear view module is advanced generally along the axis relative to and independent of the first lens.” The Examiner incorrectly contends that Yoon teaches a shaft 12 “comprising a first lens (36, Fig. 2) fixedly attached at the distal end.” (Final Action, page 6, lines 14-16, emphasis added). As readily seen in FIGS. 1 and 2 (provided above), Yoon does not teach a lens fixedly received on the shaft 12 with a hollow channel for advancing a catheter therein.

Specifically, Yoon teaches an endoscope body 12, and alternatively, a hollow tube 76 (FIGS. 5 and 6), that the Examiner contends teaches the shaft of independent claim 54. (Yoon, column 4, line 21; Final Action, page 6, line 14) Further, the Examiner states that a lens is fixedly received on the body 12. (Final Action, page 6, lines 15-16) However, Yoon teaches that an image receiver 36 is attached to each endoscope branch 14, 16, 18. (Yoon, column 4, line 57- column 5, line 2 and FIGS. 1 and 2). Each endoscope branch 14, 16, 18 is inserted through the body 12. (Yoon, FIG. 1)

Issue (e) Yoon does not teach lenses that are advanced independently

Independent claim 1 positively recites “the second lens being selectively independently advanced generally parallel to the axis relative to the first lens.” Independent claim 54 positively recites “the catheter is selectively advanced within the channel such that the rear view module is

advanced generally along the axis relative to and independent of the first lens.” In direct contrast, the endoscope branches of Yoon are taught to be advanced *simultaneously*.

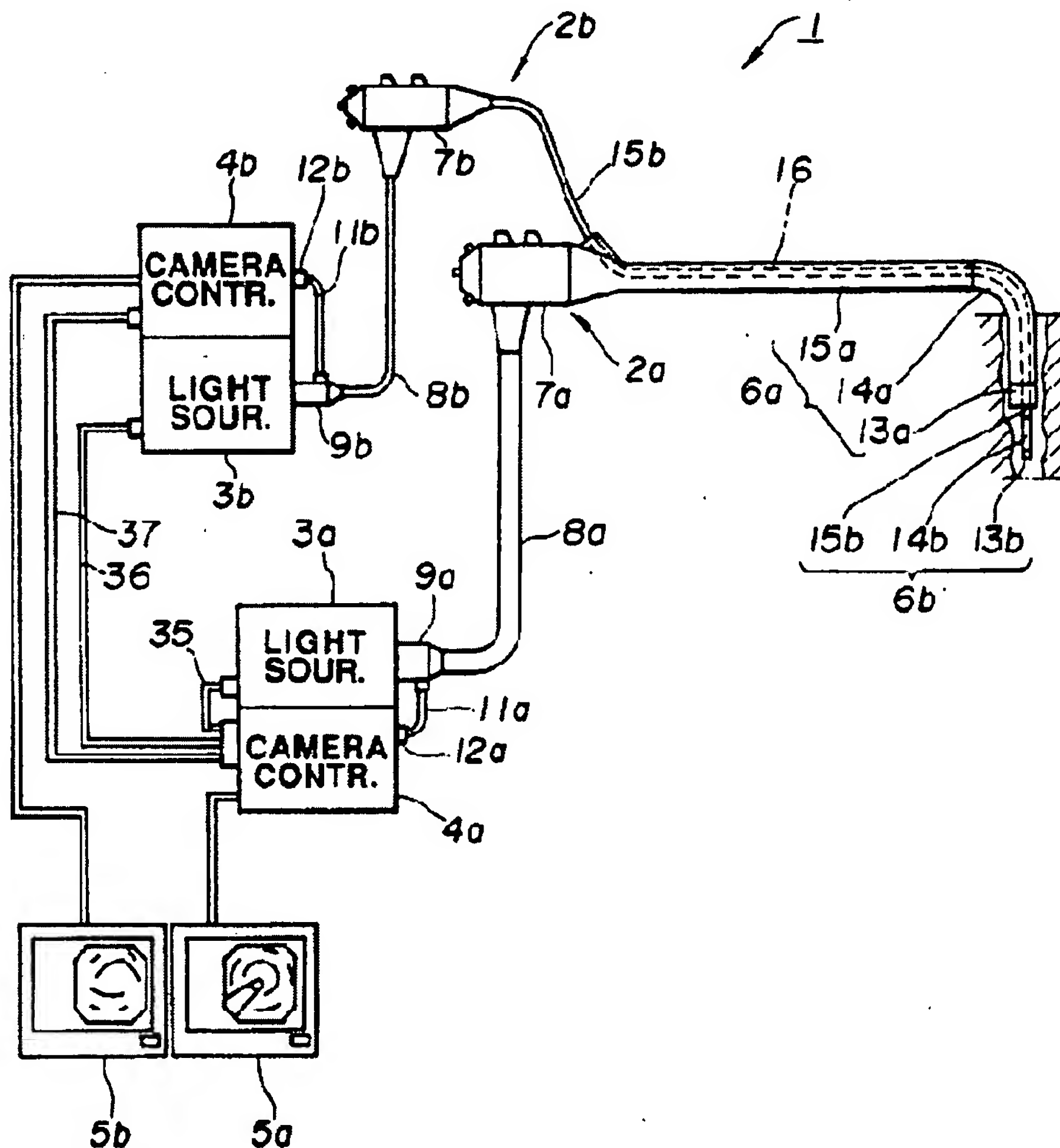
Specifically, FIGS. 4 and 5 of Yoon and column 6, lines 59-66 illustrate that the endoscope branches are not independently advanced, but are simultaneously advanced in order to have each branch view the same tissue (surgical site 70) from a different perspective. If the endoscope branches of Yoon were modified so as to advance independently, then the modified device would be wholly unsuitable for the intended purpose of Yoon, as expressly prohibited in *In re Gordon*. For at least this reason, the 35 U.S.C. §103 rejection of Appellant’s pending claims under Yoon is improper.

Issue (f) Kaiya teaches two scopes that view the same tissue

This discussion of Kaiya is presented primarily to demonstrate that the facts of *In re Gordon* are directly applicable to the proposed modification to Kaiya. In short, Kaiya teaches a system that has an intended purpose of imaging the same tissue with two different scopes, each scope using a different reflective light, to compare the two images. Tissue of interest will appear differently when the two images are compared. Therefore, the scopes of Kaiya would be inoperable for the intended purpose of Kaiya if the two scopes were to image different tissue.

FIGS. 2 and 10 of Kaiya illustrate that the image taken by the parent scope 2a and shown on monitor 5a includes a portion of the son scope 2b. (See specifically, item 5a of FIG. 2 of Kaiya, reproduced below for convenience).

FIG. 2



Accordingly, the outer endoscope 2a of Kaiya takes a forward view. Kaiya makes no mention of taking anything but a forward view from the outer endoscope 2a, nor does Kaiya discuss any mechanism for manipulating the outer endoscope such that a view other than a forward view (relative to the portion 13a) may be taken.

Issue (g) The scopes of Kaiya are taught to only view the same tissue

Kaiya teaches two videoscopes 2a, 2b that view the same tissue from the same direction (i.e. taking the same view). (See Kaiya, FIGS. 2 and 10). The complexities of the invention of Kaiya are directed toward filtering the images and synchronizing sequentially the timing of taking images to prevent an identified problem where light from one videoscope reflected from

tissue will deteriorate an image of the same tissue taken by the other videoscope. (Kaiya, Abstract; column 2, lines 37-48; and column 5, lines 29-37) While the teachings of Kaiya may not be clear from an initial reading (the translation from Japanese to English may have contributed to this), a close reading of column 5, line 45 to column 7, line 53 reveals that the two videoscopes are synchronized such that a first videoscope may output green light which is reflected by tissue for a specific image of the tissue to be taken by the first videoscope, and thereafter (sequentially) the green light and the first endoscope is turned off and the second videoscope may output red light which is reflected by the **same tissue** for a specific image of the tissue to be taken by the second videoscope. As taught in Kaiya, this prevents an undesirable situation where the green light from the *first* videoscope is reflected by the tissue and affects the image taken by the *second* videoscope. (See specifically, Kaiya, column 7, lines 43-47). This can only be the case when, as specifically illustrated in FIGS. 2 and 10 of Kaiya, the two videoscopes are imaging the same tissue.

In response to the Examiner's comments in the Examiner's Answer of August 18, 2010, page 12, line 10 to page 14, line 15, the Examiner states that "Appellant attempts to show that the two endoscopes of Kaiya ... can ONLY view the same tissue...it is assumed that this is an attempt to ..." (page 12, lines 11-13; *see also* page 14, lines 17-21). However, this assumption is incorrect. Specifically, Appellant is not attempting to evidence that the Examiner's modification to Kaiya would not work, but is illustrating that Kaiya teaches a system for a particular purpose, i.e. two endoscopes that only view the same tissue. Further, Appellant is not discussing Kaiya to argue the Examiner's interpretation of Kaiya, but rather to illustrate that the teachings of Kaiya make *In re Gordon* directly on point which PREVENTS Kaiya from being used as prior art due to the holding of *In re Gordon* (see Issues h and i). That is, Kaiya cannot be used as a 103 reference no matter how the Examiner chooses to modify the endoscopes.

Additionally, the Examiner argues that the endoscopes of Kaiya are capable of imaging in two directions (Examiner's Answer, page 13, line 10). However, *In re Gordon* is not concerned with what a device is capable of, but rather about the teachings of the reference, and when *In re Gordon* is used to exclude a reference, then the reference is not available as 35 USC 103 art and what the device may be capable of is of no import.

Issue (h) *In re Gordon* and *In re Ratti*

In re Gordon and *In re Ratti*, presented above in Section VII (A)(5), survive unmolested by *KSR* and provide that when modifying a device to cobble together a 103 rejection, the modification cannot render the device unsuitable for its intended purpose. As recently as April 26, 2010, the Board of Patent Appeals and Interfaces (BPAI) has endorsed this holding of *In re Gordon* (see *In re Chiang*, Appeal 2009-0146293 (application 10/921,604), page 5, where the BPAI cites *In re Gordon* along with *KSR*) while holding that an impermissible modification exists where the functionality of the modified device is rendered unsuitable (see *In re Chiang*, page 7).

Kaiya is **entirely** directed toward synchronizing sequentially the images taken by two endoscopes. (see the discussion for Issue (g) above). Kaiya makes no mention of how the endoscopes are directed toward the desired location and provides no details for any controls other than those for sequential synchronization. In short, Kaiya has a clear intended purpose, which is to prevent distortion of images when two videoscopes view the same tissue. If the videoscope 2b of Kaiya were modified such that the image of the videoscope 2b were taken in the opposite direction of the image of the videoscope 2a (i.e. not imaging the same tissue), then the modified device would be unsuitable for the intended purpose of Kaiya.

Therefore, Kaiya cannot be modified (using *Torii* or any other reference) such that the parent and the son endoscopes take views from opposite directions. Accordingly, and for at least this reason, the 35 U.S.C. §103 rejection of Appellant's pending claims under Kaiya is improper.

In the Examiner's remarks in the Examiner's Answer, page 14, line 17 to page 15, line 14, the Examiner focuses on what one could do to the device of Kaiya in an attempt to modify Kaiya as a 35 USC 103 reference. Appellant contends (see Issues i and j below) that Kaiya **cannot** be used as prior art when this modification is made.

Issue (i) Examiner's Remarks evince a clear misunderstanding of *In re Gordon*

The Examiner misstates the remarks provided by the Appellant in earlier responses. (See generally, Final Action, page 9).

Appellant need not argue (and does not) that the device of Kaiya would ‘stop working’ with the proposed modification. (See Final Action, page 9, lines 16-18).

Appellant need not argue (and does not) that the device of Kaiya “can *only* provide images” ... “from the **same** direction.” (See Final Action, page 9, lines 1-3, emphasis in original)

Appellant need not argue (and does not) that the device of Kaiya would not “function to generate an image” with the proposed modification. (See Final Action, page 9, lines 14-15).

Appellant **does** argue that the Federal Circuit’s holding in *In re Gordon* is directly on point in regards to the Examiner’s proposed modification to Kaiya.

To be clear, *In re Gordon* does not require that a device “stop working” in order for a modification to be impermissible, as the Examiner insists, instead *In re Gordon* requires that the teachings of the use of the device in the reference be directed to a device that, if modified to read on the pending claim, will be unsuitable for the use of the device as originally taught.

The Examiner has seemingly ignored all arguments presented with respect to *In re Gordon* in the Appeal Brief filed February 16, 2010. Specifically, in the Examiner’s Answer, the Examiner states in response to this issue “since the Examiner never previously mentions, discusses, or claims to understand *In re Gordon*, the Examiner will not comment.” Importantly, the court in *In re Gordon*, and as followed by the BPAI in *In re Chiang* in April 2010, concluded their discussion of the impermissible modification with “[i]n effect, [the prior art] teaches away from the board's proposed modification.”

Issue (j) KSR does not permit providing a motivation to defeat *In re Gordon*

The Examiner appears to provide a motivation for the proposed modification to Kaiya in page 9, lines 6-13 of the Final Action. While the Supreme Court in *KSR* rejected a rigid approach to the teaching, suggestion, motivation (TSM) test for obviousness, the Court did not introduce the rule that providing some motivation for a modification could negate other requirements for obviousness under 37 CFR 103. Importantly, the Federal Circuit addressed the issues of ‘motivation’ and ‘inoperable for intended purpose’ separately in *In re Gordon*. The

most recent revision of the Manual of Patent Examining Procedure (MPEP) incorporates *KSR* and does not delete the reference to the holding of *In re Gordon*. (MPEP 2143.01).

Accordingly, the impermissibility of modifying Kaiya to establish prima facie obviousness of claims 1 and 54 cannot be negated by identifying a motivation for the proposed modification, even if that motivation were proper under *KSR*.

In the Examiner's Answer, the Examiner appears to attempt to illustrate how Kaiya can be modified to defeat *In re Gordon*. However, *In re Gordon* works to prevent Kaiya from being used as a reference.

Issue (k) The Examiner's 'inherent' modification to Kaiya

The Examiner states "Kaiya explicitly teaches a 'curvable section for each endoscope, **inherently** providing the capability of the endoscope (2b) to be flexed so as to provide a different (second) field of view in a different direction." (Final Action, page 8, lines 12-13, **emphasis added**).

To repeat a quote from the Federal Circuit provided in Section VII A (above):

Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Mehl/Biophile International Corp. v. Milgraum, 52 USPQ2d 1303 at 1305 (Fed Cir. 1999) (*emphasis in original*).

Therefore, according to the Federal Circuit, in order for the curvable section of the endoscope 2b of Kaiya to **inherently** teach "providing the capability of the endoscope (2b) . . . to provide a different (second) field of view in a different direction," then the "natural result" flowing from 'curvable' must be for providing a different field of view. However, Appellant submits that a reasonable reading of Kaiya reveals that the endoscope 2b is contained within channel 16 of the endoscope 2a and that the endoscope 2b must be curvable in order to bend when the endoscope 2a is bent. (See specifically, Kaiya, column 3, lines 40-54 and FIG. 2). Therefore, since at least a portion of the inner endoscope 2b must be 'curvable' in order to permit

the outer endoscope 2a to be bent, then the Examiner has extrapolated the curvable capability of the inner endoscope 2b too far.

There is nothing in Kaiya to suggest that the endoscope 2b is steered or bent such that different tissue (different than the tissue viewed by the endoscope 2a) may be viewed. Further, and as detailed above in the remarks presented in Issue (h), providing a different field of view for the scope 2b runs against the teachings of Kaiya.

In explaining the reasoning for this modification to Kaiya, the Examiner states that a postulated need “**could** occur.” (Final Action, page 9, line 10, **emphasis in original**). The potential to curve the endoscope 2b relative to the endoscope 2a of Kaiya falls clearly within the above guidance from *Mehl/Biophile International Corp*, “[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” Accordingly, the Examiner’s reasoning for modifying the endoscope 2b of Kaiya runs afoul of an express prohibition of *Mehl/Biophile International Corp*. For at least this reason, the 35 U.S.C. §103 rejection of Appellant’s pending claims under Kaiya is improper.

Issue (I) Suggestion by a 35 USC §103 Reference

Generally, ‘curvable’ means capable of being curved. Merriam Webster provides (m-w.com) provides that ‘curve’ means “to have or take a turn, change, or deviation from a straight line or plane surface without sharp breaks or angularity.” Accordingly, there is nothing within the term curvable that requires a steering mechanism.

“The Examiner takes the position that this ‘curvable section’ **anticipates** a steering/actuation mechanism which will actively allow curving in a desired direction and thus allow the second direction to be at a predetermined angle to the first direction.” (Final Action, page 3, lines 9-12, **emphasis added**). If this is understood correctly by the Appellant, then the Examiner contends that Kaiya is suggesting a steering mechanism for the inner endoscope 2b merely by using the term ‘curvable’ (since “all the claim limitations must be taught or suggested by the prior art,” as required in *In re Royka*). An exhaustive reading of Kaiya reveals that Kaiya makes no mention of a steering mechanism or any other means for retroflexing the inner endoscope 2b. While the outer endoscope 2a may be steered to a desired location (either by a

steering mechanism or inserted through a permanently bent tube), this positioning of the outer endoscope 2a will dictate the position of the distal end of the inner endoscope 2b to the same desired location. Accordingly, any mechanism to steer the inner endoscope 2b relative to the outer endoscope 2a of Kaiya would add unnecessary complexity. Further, the Examiner has not articulated any reasoning as to why one of skill in the art would desire to add this unnecessary complexity.

For at least this reason, the 35 U.S.C. §103 rejection of Appellant's pending claims under Kaiya is improper.

In the Examiner's Answer page 18, line 19 to page 19, line 3, the Examiner identifies comments made in the Appeal Brief that were not well taken. Appellant profusely apologizes for any comments made that were inappropriate or mischaracterized the Examiner's comments, and these remarks have been omitted from this Reply Brief.

Issue (m) Kaiya does not teach an actuator for the inner endoscope

Claim 10 positively recites "an actuator operatively connected to the catheter for moving the catheter independent of the shaft." The Examiner states "the Examiner takes the position that, in order to be 'curvable', **each of** the endoscope and the catheter must inherently have some kind of active mechanism to provide the curvable function." (Final Action, page 4, lines 9-11, **emphasis added**). Merriam-Webster's online dictionary (Merriam-Webster.com) defines the suffix "-able" as "capable of." Accordingly, the term 'curvable' as used in Kaiya would be properly defined as "capable of being curved."

Assuming *arguendo* that an active mechanism were properly attributed to the term 'curvable', then **both** the inner endoscope and outer endoscope of Kaiya would **not** require an active mechanism to steer both endoscopes since the distal end of the inner endoscope will be directed to wherever the distal end of the outer endoscope is directed, requiring only that the outer endoscope of Kaiya include an active mechanism.

Appellant contends that 'curvable' is properly read as being a passive capability (may be curved by some outside force) rather than an active feature (each must individually include a mechanism for causing the curvable portion to bend) of the device of Kaiya. Importantly, the

Examiner appears to require that the word 'curvable' be an active feature, which Appellant submits is reading too much into the teachings of Kaiya (using Appellant's claims as a blueprint).

VIII. Claims Appendix

A copy of the claims involved in the present appeal is attached hereto as Appendix A, Subtitled "Claims Appendix".

IX. Evidence Appendix

There is no Evidence involved in the Appeal of Application Serial No. 10/711,859 and attached hereto as Appendix B.

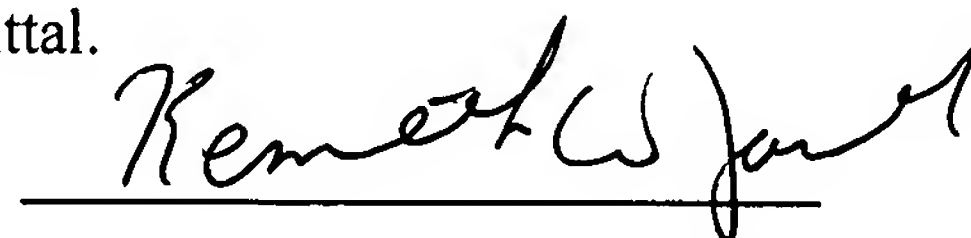
X. Related Proceedings Appendix

There are no Related Proceedings involved in the Appeal of Application Serial No. 10/711,859 and attached hereto as Appendix C.

XI. Conclusion

In view of the foregoing argument, it is submitted that the final rejections of the pending claims are improper and should not be sustained. Therefore, a reversal of the final rejections of November 13, 2009 is respectfully requested. It is believed the fees due with this appeal brief are included in an accompanying transmittal.

Dated October 18, 2010



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Appendix A

Claims Appendix

Claims involved in the Appeal of Application Serial No. 10/711,859

1. An endoscope comprising:

a shaft extending along a longitudinal axis, having a distal end receivable in a hollow organ and a proximal end and defining a hollow channel therethrough, the shaft including a steering mechanism for moving the distal end of the shaft from a first distal endoscope position to a second distal endoscope position;

a first lens selectively positioned adjacent to the distal end of the shaft for receiving a first image in a first direction, the first direction generally being forward and parallel to the longitudinal axis of the shaft and the first image generally being a circumferential view of the hollow organ;

a catheter receivable in the hollow channel of the shaft for extension and retraction therethrough, the catheter including a catheter distal end, a proximal section and a bending section interposed between the distal end and the proximal section, wherein the bending section selectively permits retroflexion of the distal end from a first position to a second position upon extension of the distal end of the catheter from the hollow channel; and

a second lens coupled to the distal end of the catheter, the second lens selectively positionable with the distal end of the shaft in the second position so as to receive a second image in a second direction, the second direction being at a generally 180 degree angle to the first direction and the second lens being selectively independently advanced generally parallel to the axis relative to the first lens.

2. (Canceled)

3. The endoscope of claim 1, wherein the first and second lenses receive the first and second images simultaneously.

4-9. (Canceled)

10. The endoscope of claim 1, further comprising an actuator operatively connected to the catheter for moving the catheter independent of the shaft.

11. (Canceled)

12. The endoscope of claim 1, wherein the second lens is operatively connected to an image processor.

13. The endoscope of claim 1, further comprising a display screen for displaying the first and second images.

14. (Canceled)

15. The endoscope of claim 1, wherein the endoscope further comprises one or more illumination bulbs disposed on the distal end of the catheter for illumination an area adjacent to the second lens.

16. The endoscope of claim 15, wherein the one or more illumination bulbs are operatively connected to a power source.

17-42 (Canceled)

43. The endoscope of claim 10, wherein the actuator includes first and second actuation members operatively connected to the distal end of the catheter, and wherein forces exerted on the actuation members selectively urge the distal end to retroflex from the first position to the second position.

44. The endoscope of claim 10, wherein the actuator for the catheter includes a bending structure disposed at the distal end of the catheter.

45-53 (Canceled)

54. An endoscope, comprising:

a first lens for selectively receiving a first image in a first direction and the first image being a view taken in the first direction;

a shaft having a distal end for fixedly receiving the first lens therein, the shaft having an axis, defining a hollow channel therethrough and having a steering mechanism to deflect the distal end for, at least in part, guiding the shaft within an organ;

a rear view module for receiving a second image in a second direction, the second direction being at an angle generally 180 degrees to the first direction and the second image being a view in the second direction, wherein the rear view module includes a second lens;

a catheter being reversibly received within the channel and having proximal and distal ends and an actuation mechanism; wherein the catheter is selectively advanced within the channel such that the rear view module is advanced generally along the axis relative to and independent of the first lens.

55. The endoscope of claim 54, wherein at least a portion of the rear view module is movable between a first position and a second position upon emerging from the hollow channel of the shaft.

56. The endoscope of claim 55, wherein the actuation mechanism is operatively connected to the distal end of the catheter for controlling movement of the rear view module.

57. The endoscope of claim 56, wherein the actuation mechanism includes first and second wires operatively connected to the distal end of the catheter, wherein forces exerted on the first and second wires selectively urge the distal end to retroflex from the first position to the second position.

58-60. (Canceled)

61. The endoscope of claim 54, wherein the second lens is operatively connected to an image processor.

62. The endoscope of claim 54, further comprising a display screen operatively connected to the first and second lenses for displaying the first and second images.

63. The endoscope of claim 54, further comprising an eyepiece operatively connected to the first and second lenses for viewing the first and second images.

64. The endoscope of claim 54, further comprising one or more illumination bulbs for illuminating an area adjacent the second lens.

65. The endoscope of claim 64, wherein the one or more illumination bulbs are operatively connected to a power source.
66. The endoscope of claim 55, wherein the rear view module is urged into the second position upon emergence from the hollow channel of the shaft by a flexible member disposed in the rear view module.
67. The endoscope of claim 10, wherein the actuator includes a bending structure disposed in the catheter and wherein the bending structure urges the catheter into the second position upon exit from the hollow channel of the shaft.
68. The endoscope of claim 43, wherein the actuation members are cables.
69. The endoscope of claim 1, wherein the distal end of the catheter has a maximum outer dimension, measured perpendicular to the axis and taken from a predetermined view when the distal end is retroflexed, that is less than an outer dimension of the shaft, measured perpendicular to the axis and taken from the predetermined view.
70. The endoscope of claim 54, wherein the distal end of the catheter has a maximum outer dimension, measured perpendicular to the axis and taken from a predetermined view when the distal end is retroflexed, that is less than an outer dimension of the shaft, measured perpendicular to the axis and taken from the predetermined view.
71. The endoscope of claim 1, wherein the first lens provides a forward view and the second lens provides a rearward view relative to the forward view during movement of the distal end of the shaft through the organ.
72. The endoscope of claim 54, wherein the first lens provides a forward view and the second lens provides a rearward view relative to the forward view during movement of the distal end of the shaft through the organ.
73. The endoscope of claim 1, wherein the first lens, when receiving the first image in the first direction, cannot view tissue that can be viewed by the second lens when receiving the second image in the second direction.
74. The endoscope of claim 54, wherein the first lens, when receiving the first image in the first direction, cannot view tissue that can be viewed by the rear view module when receiving the second image in the second direction.

Appendix B

Evidence

Evidence involved in the Appeal of Application Serial No. 10/711,859

None.

Appendix C

Related Proceedings involved in the Appeal of Application Serial No. 10/711,859

None.